



Course: Monitoring Phase I Trials: It's More than PK!

Center for Advanced Simulation and Team Training – Tulane University

<http://tulane.edu/som/sim/>

New Orleans, Louisiana

Learning Objectives: At the conclusion of this activity, the participant should be able to:

- Discuss the Phase I environment and commonly used study designs
- Define the ethical challenges of healthy-volunteers versus diseased-study populations in the early-phase environment
- Contrast perspectives of the Sponsor, IRB, Investigator, and Subject relative to ethical concerns such as group informed consent
- Identify procedures, processes, and equipment that are most commonly used in conducting early-phase studies
- Enhance site selection by identifying facility characteristics of a premier Phase I facility
- List the most frequent areas of non-compliance identified while monitoring Phase I studies
- Discuss common observations from FDA Warning letters issued during Phase I studies
- Compare differences in site monitoring activities between early and late-phase studies
- Discuss regulatory requirements unique to Phase I such as bioequivalency studies and on-site compounding
- Compare differences in drug preparation and accountability activities in the Phase I setting
- Discuss regulatory requirements unique to Phase I such as bioequivalency studies and on-site compounding
- Perform stress management techniques in the clinical research setting
- Recognize the challenges associated with 'dose-day' in a Phase I protocol

Planned

Instructors:

Lara Enzor, MS, Senior Regional Phase I Site Monitor, Johnson and Johnson Global Clinical Operations, Raritan, NJ

Sherilyn Adcock, RPh, PhD, Vice President/Chief Scientific Officer, Worldwide Clinical Trials, Austin, TX

Kellie Silvers, RPh, Business Development/former Pharmacist, CEDRA Corporation, Austin, TX

Bruce McDonald, BS, CHT, Life Skills Instructor, Aureus Research Consultants, Metairie, LA

Alicia Pouncey, MEd, Lead GCP Auditor and Instructor, Aureus Research Consultants, Metairie, LA

Day 1 Agenda

8:30-4:00PM (registration begins at 7:30AM)

1. Defining Phase I Studies and Commonly-Used Study Designs

Learn about the phase I environment, its role in drug development, the types of phase I study designs and the implications to site monitoring with each type. ADME, PK /PD, DDI....what does it all mean???? ...after this session, you should know the differences with each and what these mean to the site monitor!

2. Ethical Considerations in Phase I: The Good, The Bad, and The Ugly

What about professional subjects? How is it ethical to introduce a product into a healthy person? Is group consenting ok? Are payments to subjects appropriate, ethical? What about chronically-ill persons participating in Phase I? Interact with a Phase I Investigator regarding how these issues are viewed by the IRB/EC during early-phase development.

3. Understanding Common Procedures and Equipment Used in Phase I Studies

With lecture and use of medical simulation technologies during this group activity, you'll see, touch, and utilize common equipment used in the Phase I setting; Want to know how procedure and technique can impact data? Why do some protocols encourage non-compliance with times requested for multiple procedures? After attending this session led by Instructors with a combined 50+ years of Phase I experience, you'll learn all the tips!

Day 2 Agenda

8:30-4:00PM

4. Site Monitoring in Phase I: What's Different and Where are The Mistakes?

You know how to monitor, you just want "the differences" that come with Phase I....and here's where we'll highlight those differences! With instructors who have coordinated, monitored, and audited extensively in the Phase I setting, you're in for loads of practical advice... including common areas of non-compliance as well as best practices at monitoring electronic-source documents in the Phase I setting. We'll also utilize FDA Warning letters from the Phase I environment to further illustrate areas at risk. By utilizing case studies in both "paper" and now electronic source document environments, monitors learn best practices to become efficient while ensuring compliance!

5. Drug Preparation, Delivery, and Accountability in the Phase I Setting

Just count the pills, right? Oh, not so easy....do you know how sites "tare" a balance? Ever tried to perform accountability when there's only powder to reconcile? What's different with bioequivalence studies? What are the concerns with compounding, light-sensitive or radio-labeled products? You'll know after this session!

6. "Life Management": Managing Stress as a Clinical Research Professional

Remember when monitoring (and life) was less hectic, more fun, and you enjoyed your work! Take a break from discussions on data, timelines, and compliance and learn skills that help you "comply" with less stress, increased energy, and an understanding of the extremely positive contributions made by research professionals.

7. A Simulation of a Day in the Phase I Setting

We'll end day 2 of the course with a group simulation using medical simulation technology...instructors and course participants will "conduct" a Phase I protocol using medial simulation teaching methods. To illustrate much of what we've discussed throughout the course, we'll perform study activities often required in a Phase I protocol and under protocol timelines....all on a very important and critical point... DOSE-DAY! What better-teacher than real-life experience...don't worry though, no "invasive procedures"...but we will "invade" into the detailed-process of what really happens in the Phase I setting! You don't want to miss this one!